Exhibit I

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO WAVE 1**	**Master File No. 2:12-MD-02327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

steel, single use introducers are used to deliver the implant. The introducers are supplied fixed to the implant via a wire through the coated ends and inserters.

The GYNECARE TVT SECUR System does not change the intended use of the application of the TVT tape.

QUESTION

Does the submission include clinical information? - No[35]

100. Section 5 of the 510(k) is the 510(k) Summary, also with reference to Ms. Hojnoski, who again not adequately inform the FDA that there is a significant change in the method of operation for the surgeon to implant the device and the size (8cm) and elasticity of the sling implanted in a patient compared to TVT products, untested holding forces for Ethisorb Dura Patch in the pelvis, change to laser cutting of the mesh, raising new issues of safety and effectiveness. Instead, the FDA is told that the device "meets the established performance requirements" but with no statement that would include a safe and effective device for permanent implantation in a patient. The conclusion implies – but does not state- there are no new and unaddressed issues of safety and effectiveness which have not already been seen in the TVT or TVT-O predicates:

Technological Characteristics:

The modified device has the same technological characteristics as the predicate device. The form, fit, function and method of operation are similar.

Performance Data:

Results of verification testing indicates that the product meets the established performance requirements.

Conclusion

Based upon the 510(k) summaries and 510(k) statements (21 C.F.R. 807) and the information provided herein, we conclude that the subject device is substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.[36]

101. Section 6 is Ethicon's "Truthful and Accuracy Statement" which is required by 21 C.F.R. § 807.87(k) to be in the 510(k) submission. Ethicon's statement was signed by Patricia M. Hojnoski and dated August 30, 2005. The presence of this signed statement from Ethicon, the knowledgeable expert for the product, supports for FDA's ODE reviewers it can trust the quality and accuracy of the information provided to the agency in the 510(k). Ethicon has assured the FDA that its 510(k) is truthful, accurate and that "no material fact has been omitted". This statement must be signed by an employee of Ethicon and it cannot be signed by an outside consultant. To provide a false certification or to leave out 'material facts' about the product or products in general from the 510(k) becomes a crime against the

[35] ETH.MESH.07876572
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